C/2025/4737

8.9.2025

Request for a preliminary ruling from the Bundesverwaltungsgericht (Germany) lodged on 27 May 2025 – R. SpA v Bundesrepublik Deutschland

(Case C-354/25, Waisrinter [1])

(C/2025/4737)

Language of the case: German

Referring court

Bundesverwaltungsgericht

Parties to the main proceedings

Applicant, appellant and appellant on a point of law: R. SpA

Defendant, respondent and respondent on a point of law: Bundesrepublik Deutschland

Intervener: A. AG

Question referred

1. Do the labelling requirements laid down in Articles 54, 55(3) and 63(1) of Directive 2001/83/EC [2] apply to a medicinal product for which a marketing authorisation has been issued in a Member State and the importation of which into another Member State constitutes a parallel import in relation to a medicinal product already covered by a marketing authorisation in that second Member State?

2. Must Article 63(3) of Directive 2001/83/EC be interpreted as meaning that a medicinal product is not intended to be delivered directly to the patient if it is classified as a medicinal product subject to medical prescription?

3. Does Article 63(3) of Directive 2001/83/EC have direct effect, meaning that an operator wishing to import into Germany a medicinal product from another Member State may rely on that provision before the German courts against the defendant Federal Republic of Germany which has not transposed that provision into national law or has not transposed it fully?

4. Do Articles 34 and 36 TFEU preclude provisions of national and of EU law, which require the labelling of immediate packaging with certain minimum particulars in the language of the Member State of importation, being applied to a medicinal product imported in parallel, if it is not possible to relabel the immediate packaging of the medicinal product imported in parallel in order to comply with those labelling requirements because of a significant impairment to its shelf life which would result from this?

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[1] The name of the present case is a fictitious name. It does not correspond to the real name of any party to the proceedings.

[2] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67).